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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,648	12/21/2001	Robin Thurmond	ORT-1555	3745

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Philip S. Johnson, Esq.  
Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003

EXAMINER
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MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/036,648

Applicant(s)

THURMOND ET AL.

Examiner

Joseph F Murphy

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1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 16-22 and 27-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-15 and 23-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11102003</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-4, 12-15 and 23-26 in the reply filed 03/23/2004 is acknowledged. Claims 5-11, 16-22, 27-33 are withdrawn from consideration pursuant to 37 CFR 1.142(b).

### ***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 12-15, 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claims 1, 12 and 23 lack a step whereby the receptor activity that is modulated by the compound relates to the conclusion. For example in claim 1, step (b), the measurement is of measuring an effect of the compound on the receptor protein function, but it is not clear how this relates to the conclusion, which is modulation of inflammation. This is also the case in claims 12 and 23, wherein the measuring step does not relate to the modulated effect of, respectively, PMN activation and mast cell activation. In addition, claims 1, 12 and 23 are indefinite in their recitation as methods because there is an absence of a resolution step which reads back on the preamble of the claimed methods. Claims 2-4, 13-15, 24-26 are vague and indefinite insofar as they depend on the indefinite method of claims 1, 12 and 23.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 01/92485

(Lovenberg et al.).

The instant claims are drawn to a method of identifying compounds that modulate the mammalian histamine H4 receptor protein activity by combining a test compound with the H4 receptor in the presence of a known ligand and measuring the function of the protein. The measurement is of inflammation or of a second messenger such as cAMP. The '485 document teaches the cloning and expression of the histamine H4 receptor ('485 at 2). The '485 document further teaches a method of identifying compounds that modulate the mammalian histamine H4 receptor protein activity by combining a test compound with the H4 receptor protein (see claim 17, page 59) in the presence of a known H4 ligand (see claim 18, page 59) and measuring an H4 receptor intracellular second messenger (see claim 19, page 54), such as cAMP (see claim 20, page 60). The '485 document further teaches that histamine mediates inflammatory and allergic responses (page 27, lines 17-21). Claims 1-4 are thus anticipated.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 12-15, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/92485 (Lovenberg et al.), in view of U.S. Patent No. 5,000,936 (Chibret).

The instant claims are drawn to a method of identifying compounds that modulate the mammalian histamine H4 receptor protein activity by combining a test compound with the H4 receptor in the presence of a known ligand and measuring the function of the protein. The measurement is of inflammation, PMN activation or mast cell activation, or of a second messenger such as cAMP. The '485 document teaches the cloning and expression of the histamine H4 receptor ('485 at 2). The '485 document further teaches a method of identifying compounds that modulate the mammalian histamine H4 receptor protein activity by combining a test compound with the H4 receptor protein (see claim 17, page 59) in the presence of a known H4 ligand (see claim 18, page 59) and measuring an H4 receptor intracellular second messenger (see claim 19, page 54), such as cAMP (see claim 20, page 60). The '485 document further teaches that histamine mediates inflammatory and allergic responses (page 27, lines 17-21).

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However, while the '485 document teaches that histamine mediates inflammatory and allergic reactions, it does not specifically teach the measurement of PMN or mast cell activation. The '936 patent discloses that "allergy" has become synonymous with Type I hypersensitivity in which the reactions are dependent on the specific triggering of immunoglobulin E (IgE) - sensitized mast cells by antigen resulting in the degranulation of mast cells and the release of pharmaceutical mediators of inflammation, such as histamine. The vasoactive amine histamine from the mast cells and basophils, increases vascular permeability and attracts polymorphs (column 1, line 43 to column 2, line 10). Thus it would have been obvious to one of skill in the art at the time the invention was made to practice a method of identifying compounds that modulate the mammalian histamine H4 receptor protein activity by combining a test compound with the H4 receptor in the presence of a known ligand and measuring the function of the protein, as taught by the '485 document, wherein measurement is of allergic activity such as PMN activation or mast cell activation, as disclosed in the '936 patent. The motivation is provided in the '485 document which teaches that the mammalian H4 histamine receptor may be used to identify new agonist or antagonists which may be used as therapeutics to treat disorders directly or indirectly involving histamine receptors (see the '485 document at page 28).

### ***Conclusion***

No claim is allowed.

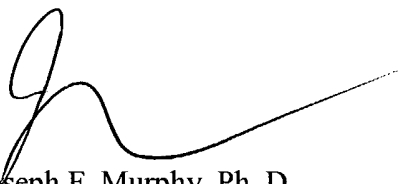
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*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'J. Murphy', with a long horizontal flourish extending to the right.

Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
May 26, 2004